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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/017,306	12/13/2001	Kevin P. Baker	GNE.2830P1C66	7268

7590 07/26/2004

EXAMINER
BUNNER, BRIDGET E

ART UNIT	PAPER NUMBER
1647	

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DATE MAILED: 07/26/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/017,306	BAKER ET AL.	
	Examiner	Art Unit	
	Bridget E. Bunner	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 March 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *27 and 28* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *28-47* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *31 December 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *11/14/02*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of Application, Amendments and/or Claims

The amendments of 31 December 2001, 10 June 2002, and 09 September 2002 have been entered in full. Claims 1-27 are cancelled and claims 28-47 are added.

Claims 28-47 are under consideration in the instant application.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on 14 November 2002 has been considered by the examiner. However, since the Blast results cited therein are not true publications with a publication date, they are not fully in compliance with 37 CFR 1.97 and thus they will not be printed on the face of the patent issuing from this application.

Specification

1. The disclosure is objected to because of the following informalities:

2. The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code (See pg 304, line 5; pg 306, line 23). Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

3. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

Appropriate correction is required.

Claim Rejections - 35 USC § 101 and 35 USC § 112

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 28-47 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a credible, specific and substantial asserted utility or a well established utility. Novel biological molecules lack well established utility and must undergo extensive experimentation.

Specifically, claims 28-47 are directed to an isolated nucleic acid having at least 80%, 85%, 90%, 95%, and 99% nucleic acid sequence identity to (a) a nucleic acid sequence encoding the polypeptide shown in Figure 220 (SEQ ID NO: 376), (b) a nucleic acid sequence encoding the polypeptide shown in Figure 220 (SEQ ID NO: 376) lacking its associated signal peptide, (c) a nucleic acid sequence encoding the extracellular domain of the polypeptide shown in Figure 220 (SEQ ID NO: 376), (d) a nucleic acid sequence encoding the extracellular domain of the polypeptide shown in Figure 220 (SEQ ID NO: 376) lacking its associated signal peptide, (e) a nucleic acid sequence shown in Figure 219 (SEQ ID NO: 375), (f) the full-length coding sequence of the nucleic acid sequence shown in Figure 219 (SEQ ID NO: 375), or (g) the full-length coding sequence of the cDNA deposited under ATCC accession number 203473. The claims are directed to an isolated nucleic acid comprising the previously mentioned subparts (a), (b), (c), (d), (e), (f), or (g). The claims also recite a vector and host cell.

The specification discloses that "many efforts are focused on the screening of mammalian recombinant DNA libraries to identify the coding sequences for novel secreted proteins. We herein describe the identification and characterization of a novel secreted protein designated

herein as PRO1760" (pg 31, lines 29-31) However, the instant specification does not teach any significance or functional characteristics of the PRO1760 polynucleotide (SEQ ID NO: 375) or polypeptide (SEQ ID NO: 376). The specification also does not disclose any methods or working examples that indicate the polynucleotides and polypeptide of the instant invention are involved in any activity. Since significant further research would be required of the skilled artisan to determine how the claimed polynucleotide and polypeptide are involved in any activities, the asserted utilities are not substantial. Since the utility is not presented in mature form and significant further research is required, the utility is not substantial. The specification asserts the following as patentable utilities for the claimed putative nucleic acid (SEQ ID NO: 375):

1) as hybridization probes for cDNA and genomic DNA (pg 364, lines 25-39)

2) for antisense or sense oligonucleotides (pg 365, lines 2-39; pg 366, lines 1-6)

3) in chromosome and gene mapping/identification (pg 366, lines 7-11; pg 368, lines 8-11)

4) to identify proteins or other molecules involved binding interactions (pg 366, lines 12-22)

5) to generate transgenic or "knock out" animals (pg 366, lines 23-39; pg 367, lines 1-18)

6) in gene therapy (pg 367, lines 19-39; pg 368, lines 1-4)

7) in tissue typing (pg 368, lines 12-15)

8) inhibition of glucose uptake by rat adipocytes (pg 511, lines 34-39 through pg 512, lines 1-10)

9) inhibition heart neonatal hypertrophy (pg 514, lines 24-25)

Each of these shall be addressed in turn.

1) as hybridization probes for cDNA and genomic DNA. This asserted utility is not substantial or specific. Hybridization probes can be designed from any nucleic acid sequence. Further, the specification does not disclose specific cDNA, DNA, or RNA targets. Since this asserted utility is also not present in mature form, so that it could be readily used in a real world sense, the asserted utility is not substantial.

2) for antisense or sense oligonucleotides. This asserted utility is not specific or substantial. Antisense oligonucleotides can be designed from any nucleic acid sequence. Further, the specification does not disclose a specific DNA/RNA target. Since this asserted utility is also not present in mature form, so that it could be readily used in a real world sense, the asserted utility is not substantial.

3) in chromosome and gene mapping/identification. This asserted utility is not specific or substantial. Such assays can be performed with any nucleic acid. Further, the specification does not disclose a specific DNA target. Since this asserted utility is also not present in mature form, so that it could be readily used in a real world sense, the asserted utility is not substantial.

4) to identify proteins or other molecules involved binding interactions. This asserted utility is not specific or substantial. Such assays can be performed with any nucleic acid. Additionally, the specification discloses nothing specific or substantial for the proteins or other molecules that can be identified by this method. Since this asserted utility is also not present in mature form, so that it could be readily used in a real world sense, the asserted utility is not substantial.

5) to generate transgenic or "knock out" animals. This asserted utility is not specific or substantial. The specification does not disclose diseases associated with a mutated, deleted, or translocated PRO1760 gene (SEQ ID NO: 375). Significant further experimentation would be

required of the skilled artisan to identify such a disease. The specification discloses nothing about whether the gene will be "knocked in" or "knocked out" or what specific tissues and cells are being targeted. Since this asserted utility is also not present in mature form, so that it could be readily used in a real world sense, the asserted utility is not substantial.

6) in gene therapy. This asserted utility is not specific or substantial. Such can be performed for any nucleic acid. Further, the specification does not disclose diseases associated with a mutated, deleted, or translocated PRO1760 gene (SEQ ID NO: 375). Significant further experimentation would be required of the skilled artisan to identify individuals with such a disease and to determine the route of administration of the gene, as well as quantity and duration of treatment. Since this asserted utility is also not presented in mature form, so that it could be readily used in a real world sense, the asserted utility is not substantial.

7) in tissue typing. This asserted utility is specific or substantial. Such assays can be performed with any nucleic acid. Further, the specification does not disclose specific DNA sequences for use as markers for RFLP, to prepare primers, or to amplify DNA. Since this asserted utility is also not present in mature form, so that it could be readily used in a real world sense, the asserted utility is not substantial.

8) inhibition of glucose uptake by rat adipocytes. This asserted utility is not substantial. The specification teaches that "as the PRO polypeptide being tested may either stimulate or inhibit glucose and FFA uptake, results are scored as positive in the assay is greater than 1.5 times or less than 0.5 times the insulin control" (pg 512, lines 4-6). Although the specification teaches that PRO1760 is positive as an inhibitor in this assay, the specification does not disclose any specific resulting cell numbers or percentages, statistical differences, or the number of repetitions for the assay. Without this knowledge, which could not be gleaned from the instant

specification, one of ordinary skill in the art at the time the invention was made would not have been able to use the information obtained from this assay in a useful manner. One skilled in the art would be unable to repeat the assay with a compound (such as one of the PRO1760 variants encompassed by the claims) and determine whether the compound scored positive or negative. Since this asserted utility is also not present in mature form, so that it could be readily used in a real world sense, the asserted utility is not substantial. Furthermore, the specification of the instant application teaches that PRO polypeptides that inhibit glucose uptake by adipocytes would be beneficial for the therapeutic treatment of disorders including for example, obesity, diabetes, or hyper- or hypo-insulinemia (pg 511, lines 18-20). However, it is not clear how PRO1760, which inhibits glucose uptake as asserted by the specification, is beneficial to such disorders because in these conditions little or no glucose is entering the cells to begin with. The cells are unable to utilize glucose. Therefore, why would one skilled in the art want to exacerbate this situation even more by the addition of PRO1760?

9) inhibition heart neonatal hypertrophy. This asserted utility is not specific or substantial. The specification teaches that "a positive in the assay occurs when the PRO polypeptide treated myocytes are visually smaller on the average or less numerous than the untreated myocytes" (pg 514, lines 33-34). Although the specification teaches that PRO1760 is positive in this assay, the specification does not disclose any specific resulting cell numbers, statistical differences, or the number of repetitions for the assay. For example, there is no indication in the specification as to statistically how much smaller the PRO polypeptide treated myocytes are as compared to control. Without this knowledge, which could not be gleaned from the instant specification, one of ordinary skill in the art at the time the invention was made would not have been able to use the information obtained from this assay in a useful manner. One

skilled in the art would be unable to repeat the assay with a compound (such as one of the PRO1760 variants encompassed by the claims) and determine whether the compound scored positive or negative. Since this asserted utility is also not present in mature form, so that it could be readily used in a real world sense, the asserted utility is not substantial. Furthermore, PRO1760 may not necessarily inhibit the neonatal heart hypertrophy condition itself, but rather, simply bind LIF or ET-1, which are the factors utilized to induce the hypertrophy. The state of the art is also such that a rat cardiac myocyte cell culture is not an art recognized model for heart hypertrophy, but instead is used to "explore the regulation of myocardial cell hypertrophy" (Simpson et al., Circ Res 51(6): 787-801, 1982; last sentence in abstract; Ueyama et al., J Mol Cell Cardiol 32: 947-960, 2000).

5. Claims 28-47 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

6. Furthermore, claims 28-32 and 41-47 are directed to an isolated nucleic acid having at least 80%, 85%, 90%, 95%, and 99% nucleic acid sequence identity to (a) a nucleic acid sequence encoding the polypeptide shown in Figure 220 (SEQ ID NO: 376), (b) a nucleic acid sequence encoding the polypeptide shown in Figure 220 (SEQ ID NO: 376) lacking its associated signal peptide, (c) a nucleic acid sequence encoding the extracellular domain of the polypeptide shown in Figure 220 (SEQ ID NO: 376), (d) a nucleic acid sequence encoding the extracellular domain of the polypeptide shown in Figure 220 (SEQ ID NO: 376) lacking its associated signal peptide, (e) a nucleic acid sequence shown in Figure 219 (SEQ ID NO: 375),

(f) the full-length coding sequence of the nucleic acid sequence shown in Figure 319 (SEQ ID NO: 375), or (g) the full-length coding sequence of the cDNA deposited under ATCC accession number 203473. The claims also recite an isolate nucleic acid that hybridizes to (a), (b), (c), (d), (e), (f), or (g). The claims recite a vector comprising the nucleic acid and a host cell comprising the vector.

The specification teaches that the term "'PRO/number polypeptide' and 'PRO/number' wherein the term 'number' is provided as an actual numerical designation as used herein encompass native sequence polypeptides and polypeptide variants. The PRO1760 nucleic acids and polypeptides described herein may be isolated from a variety of sources, such as from human tissue types or from another source, or prepared by recombinant or synthetic methods (pg 301, lines 6-8). The specification discloses that a PRO variant polynucleotide or PRO variant nucleic acid sequence is defined as a nucleic acid molecule which encodes an active PRO polypeptide and which has at least about 80% nucleic acid sequence identity with a nucleotide acid sequence encoding a full-length native sequence PRO polypeptide sequence, a full-length native sequence PRO polypeptide sequence lacking the signal peptide, an extracellular domain of a PRO polypeptide, with or without signal peptide, or any other fragment of a full-length PRO polypeptide sequence (pg 302, lines 4-32). However, the specification does not teach any variant, fragment, or derivative of the PRO1760 nucleic acid other than the full-length nucleic acid sequence of SEQ ID NO: 375. The specification also does not teach functional or structural characteristics of the nucleic acid variants, fragments, and derivatives recited in the claims.

The problem of predicting protein and DNA structure from sequence data and in turn utilizing predicted structural determinations to ascertain functional aspects of the protein and DNA is extremely complex. While it is known that many amino acid substitutions are generally

possible in any given protein the positions within the protein's sequence where such amino acid substitutions can be made with a reasonable expectation of success are limited. Certain positions in the sequence are critical to the protein's structure/function relationship, e.g. such as various sites or regions directly involved in binding, activity and in providing the correct three-dimensional spatial orientation of binding and active sites. These or other regions may also be critical determinants of antigenicity. These regions can tolerate only relatively conservative substitutions or no substitutions (see Wells, 1990, Biochemistry 29:8509-8517; Ngo et al., 1994, The Protein Folding Problem and Tertiary Structure Prediction, pp. 492-495). However, Applicant has provided little or no guidance beyond the mere presentation of sequence data to enable one of ordinary skill in the art to determine, without undue experimentation, the positions in the DNA and protein which are tolerant to change (e.g. such as by amino acid substitutions or deletions), and the nature and extent of changes that can be made in these positions. Even if an active or binding site were identified in the specification, they may not be sufficient, as the ordinary artisan would immediately recognize that an active or binding site must assume the proper three-dimensional configuration to be active, which conformation is dependent upon surrounding residues; therefore substitution of non-essential residues can often destroy activity. The art recognizes that function cannot be predicted from structure alone (Bork, 2000, Genome Research 10:398-400; Skolnick et al., 2000, Trends in Biotech. 18(1):34-39, especially p. 36 at Box 2; Doerks et al., 1998, Trends in Genetics 14:248-250; Smith et al., 1997, Nature Biotechnology 15:1222-1223; Brenner, 1999, Trends in Genetics 15:132-133; Bork et al., 1996, Trends in Genetics 12:425-427).

Due to the large quantity of experimentation necessary to generate the infinite number of derivatives recited in the claims and possibly screen same for activity, the lack of

direction/guidance presented in the specification regarding which structural features are required in order to provide activity, the absence of working examples directed to same, the complex nature of the invention, the state of the prior art which establishes the unpredictability of the effects of mutation on protein structure and function, and the breadth of the claims which fail to recite any structural or functional limitations, undue experimentation would be required of the skilled artisan to make and/or use the claimed invention in its full scope.

7. Claims 28-32 and 41-47 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are directed to an isolated nucleic acid having at least 80%, 85%, 90%, 95%, and 99% nucleic acid sequence identity to (a) a nucleic acid sequence encoding the polypeptide shown in Figure 220 (SEQ ID NO: 376), (b) a nucleic acid sequence encoding the polypeptide shown in Figure 220 (SEQ ID NO: 376) lacking its associated signal peptide, (c) a nucleic acid sequence encoding the extracellular domain of the polypeptide shown in Figure 220 (SEQ ID NO: 376), (d) a nucleic acid sequence encoding the extracellular domain of the polypeptide shown in Figure 220 (SEQ ID NO: 376) lacking its associated signal peptide, (e) a nucleic acid sequence shown in Figure 219 (SEQ ID NO: 375), (f) the full-length coding sequence of the nucleic acid sequence shown in Figure 319 (SEQ ID NO: 375), or (g) the full-length coding sequence of the cDNA deposited under ATCC accession number 203473. The claims also recite an isolate nucleic acid that hybridizes to (a), (b), (c), (d), (e), (f), or (g). The claims recite a vector comprising the nucleic acid and a host cell comprising the vector. The claims do not

require that the nucleic acid or polypeptide possess any particular biological activity, nor any particular conserved structure, or other disclosed distinguishing feature. Thus, the claims are drawn to a genus of nucleic acids that is defined only by sequence identity.

To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of compete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof. In this case, the only factor present in the claim is a partial structure in the form of a recitation of percent identity. There is not even identification of any particular portion of the structure that must be conserved. Accordingly, in the absence of sufficient recitation of distinguishing identifying characteristics, the specification does not provide adequate written description of the claimed genus. Additionally, the description of one polynucleotide species (SEQ ID NO: 375) and one polypeptide species (SEQ ID NO: 376) is not adequate written description of an entire genus of functionally equivalent polynucleotides and polypeptides which incorporate all variants and fragments and with at least 80%, 85%, 90%, 95%, and 99% sequence identity to a nucleic acid comprising the sequence of SEQ ID NO: 375.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed"* (See page 1117). The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed" (See *Vas-Cath* at page 1116).

With the exception of the sequences referred to above, the skilled artisan cannot envision the detailed chemical structure of the encompassed polynucleotides, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The nucleic acid itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481 at 1483. In *Fiddes*, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence.

Therefore, only an isolated nucleic acid consisting of the sequence of SEQ ID NO: 375, but not the full breadth of the claim meets the written description provision of 35 U.S.C. §112, first paragraph. Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

35 USC § 112, second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 28-34, 36-37 and 41-47 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

9. Regarding claims 28-34, 36-37 and 41-47, the protein identified as PRO1760 (SEQ ID NO: 376) is a soluble, secreted protein, and is not disclosed as being expressed on a cell surface (see pg 31, lines 27-31 of the specification, for example). Accordingly, the limitation that the claimed nucleic acid sequence encoding the "extracellular domain" of the polypeptide shown in Figure 220 (SEQ ID NO: 376) (for example see claim 28 parts (c) and (d)) is indefinite, as the art does not recognize soluble proteins as having such domains. Further, if the protein had an extracellular domain, the recitation of "the extracellular domain"... "lacking its associated signal sequence" (claim 28, part (d), for example) is indefinite as a signal sequence is not generally considered to be part of an extracellular domain, as signal sequences are cleaved from said domains in the process of secretion from the cell.

10. Also, regarding claim 42, stringency is relative, and the art does not recognize a single set of conditions as stringent. The specification also does not provide an unambiguous definition for the term. In the absence of a recitation of clear hybridization conditions (e.g., "hybridizes at wash conditions of **A** X SSC and **B** % SDS at **C**°C"), claim 42 fails to define the metes and bounds of the varying structures of polynucleotides recited in the claimed methods.

11. Claim 46 is rejected as being indefinite because it cannot be determined if the host cell encompasses an isolated or cultured cell or a transgenic organism. It is noted that this issue could be overcome by amending the claim to recite, for example, "An isolated host cell".

Priority

Applicant's claim for priority under 35 U.S.C. 120 and 119(e) is acknowledged. The instant application claims priority to 09/946, 374 (9/4/2001), PCT/US000/04342 (2/18/2000), 09/403,297 (10/18/1999), PCT/US99/2011 (9/1/1999), and 60/108,787 (11/17/1998). The applications upon which priority is claimed fails to provide adequate support under 35 U.S.C. §

112 for claims 28-47 of this application. Also, the instant specification fails to provide a disclosure meeting the requirements of 35 U.S.C. § 101 and § 112, first paragraph. However, the polynucleotide of SEQ ID NO: 60 of the instant application is fully disclosed in the prior applications and the filing date of 17 November 1998 has been used for the purposes of applying the prior art below.

Claim Rejections - 35 USC § 102

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

13. Claims 28-31 and 41-47 are rejected under 35 U.S.C. 102(a) as being anticipated by Ruben et al. (U.S. Patent 6,475,753).

Ruben et al. teach an isolated nucleic acid having at least 95.9% nucleic acid sequence identity to the nucleic acid sequence of SEQ ID NO: 375 of the instant application. (Please see Appendix A attached to this Office Action; see nucleotides 80-1161 of SEQ ID NO: 60 of Ruben et al. and nucleotides 1-1088 of SEQ ID NO: 375 of the instant application.) Ruben et al. also disclose that the nucleic acid may be joined to a vector and that the nucleic acid is operably linked to control sequences (col 189, lines 4-23). Ruben et al. teach that a host cell may comprise the vector and nucleic acid molecule (col 189, lines 48-56). Ruben et al teach that the host cell may be a yeast cell, among others (col 190, lines 1-6). (It is noted that Ruben et al. first discloses the full length polynucleotide of SEQ ID NO: 60 in provisional application 60/089,508, filed 6/16/1998, and therefore this date has been used for purposes of applying art.)

Conclusion

No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bridget E. Bunner whose telephone number is (571) 272-0881. The examiner can normally be reached on 8:30-4:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on (571) 272-0961. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Elizabeth C. Kemmerer

BEB
Art Unit 1647
21 July 2004

ELIZABETH KEMMERER
PRIMARY EXAMINER